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| 10/507,490 | 08/22/2005 | Meir Shinitzky | SHINITZKY8 | 8573 |

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

| EXAMINER | |
|---|---|
| SHIAO, REI TSANG | |

| ART UNIT | PAPER NUMBER |
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| 1626 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/507,490 | SHINITZKY, MEIR | |
| | Examiner | Art Unit | |
| | Rei-tsang Shiao, Ph.D. | 1626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. This application claims benefit of the foreign application:

ISREAL 148665 with a filing date 03/13/2002.

2. Claims 15-28 are pending in the application.

### *Information Disclosure Statement*

3. Applicant's Information Disclosure Statement, filed on September 22, 2005 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-25 and 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using compounds of the formula (I) for treating neural cells, *in vitro*, does not reasonably provide enablement for treating or preventing neural activity or diseases using compounds of formula (I), *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first

paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

In the instant case:

**The nature of the invention**

The nature of the invention of claims 21-25 and 27-28 is drawn to a pharmaceutical composition with intent methods of use using compounds of the formula (I) for treating or preventing neural activity or diseases.

**The state of the prior art and the predictability or lack thereof in the art**

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in

the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face. Shinitzky's US 6,914,056 discloses similar compound for treating PC12 cell *in vitro*.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833,166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming a pharmaceutical composition with intent methods of use using compounds of the formula (I) effective to "treating or preventing neural activity or diseases". As such, the specification fails to enable the skilled artisan to use the compounds of claims effective to "treating or preventing neural activity or diseases".

In addition, there is no established correlation between *in vitro* or in *vivo* activity and accomplishing treatment of "treating or preventing neural activity or diseases", and those skilled in the art would not accept allegations in the instant specification to be reliable predictors of success, and those skilled in the art would not be able to use compounds of the formula (I) since there is no description of an actual method wherein "treating or preventing neural activity or diseases" in a host is treated or prevented.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the compounds/compositions of claims 21-25 and 27-28 due to the unpredictability of the "treating or preventing neural activity or diseases". The "treating

or preventing neural activity or diseases" is known to have many obstacles that would prevent one of ordinary skill in the art from accepting treating regimen on its face.

**The amount of direction or guidance present and the presence or absence of working examples**

The only direction or guidance present in the instant specification is the listing of exemplary patient test of treating neural cells (i.e., PC12 cells), *in vitro*, see Examples 19-22 in pages 17-21 of the specification. There are no *in vivo* working examples present for the treatment or prevention of any neural activity or diseases by the administration of the instant invention.

**The breadth of the claims**

The breadth of the claims is methods of use of the instant compounds effective to "treating or preventing neural activity or diseases" (i.e., no *in vivo* data). Furthermore, the instant claims cover "treating or preventing neural activity or diseases" that are known to exist and those that may be discovered in the future, for which there is no enablement provided. Moreover, there is no reasonable basis for assuming the instant compounds of the formula (I) embraced by the claims will share the same physiological properties.

**The quantity of experimentation needed**

The quantity of experimentation needed is undue experimentation. One of skill in

the art would need to determine what "treating or preventing neural activity or diseases" would be benefited (i.e., treated or prevented) by the administration of the instant compounds of the formula (I) of the instant invention and would furthermore then have to determine which of the claimed composition with intent methods of use would provide treatment of a disease, if any.

**The level of the skill in the art**

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which methods of use exhibit the desired pharmacological activity and which diseases would benefit from this activity. Thus, the specification fails to provide sufficient support of the broad use of the pharmaceutical compounds of the instant claims for the "treating or preventing neural activity or diseases".

As a result necessitating one of skill to perform an exhaustive search for which "treating or preventing neural activity or diseases", can be treated or prevented by what pharmaceutical compounds of the instant claims in order to practice the claimed invention. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds in regards to the treatment of the many diseases resulting from "treating cell disorders by promoting cell differentiation" without limitation, one having ordinary

skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by incorporation of the treating conditions (i.e., *in vitro*) or deletion of the preamble "treating or preventing neural activity or diseases " respectively would obviate the rejection.

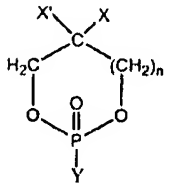
### *Claim Rejections - 35 USC § 102*

**5**. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Applicants claims 1,3-cyclic propanediol phosphate compounds/compositions of the formula (I), i.e.,



, wherein the variable n is 1, see claim 15.

**6.1** Claims 15-28 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Shinitzky's US 6,914,056 or US 6,872,712. Shinitzky's '056 or '712 is 102(e) reference.

Shinitzky's '056 or '712 respectively disclose a number of 1,3-cyclic propanediol phosphate compounds, see formula (I) and (IV) in columns 14-15 of Shinitzky's '056 or columns 20-21 of Shinitzky's '712. Shinitzky's compounds clearly anticipate the instant compounds of formula (I), wherein the variable n is 1, the variable X or X' independently represents hydrogen,CH2OH, OR and R is H, the variable Y is O-R1 and R1 is hydrogen or aryl (i.e., phenyl).

**6.2** Claims 15-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mallamo et al. CAS: 126:212447.

Mallamo et al. disclose a compound, see RN: 187976-16-5, it clearly anticipates the instant compounds of formula (I), wherein the variable n is 1, the variable X or X'

independently represents hydrogen or OR and R is aralkyl, the variable Y is O-R1 and R1 is hydrogen.

***Double Patenting***

**7.** A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 19 and 26 (i.e., the compounds No. (a)-(h) and (j)-(p)) are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19 and 24 respectively of Shinitzky's co-pending application No. 10/507,489. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

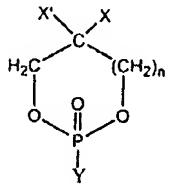
**8**. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

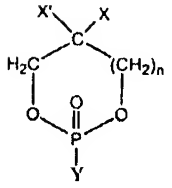
**9**. Claims 15-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of Shinitzky's co-pending application No. 10/507,489. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claims compounds/compositions of the formula (I), i.e.,



, wherein the variable n is 1, see claim 15.

Shinitzky's claims compounds/compositions of the formula (I), i.e.,



, wherein the variable n is 0 or 1.

The difference between the instant claims and Shinitzky's is that the instant variables n represents 1, while Shinitzky's represents 0 or 1 at the same position. Shinitzky's compounds/compositions overlap with the instant invention.

One having ordinary skill in the art would find the instant claims 15-28 prima facie obvious **because** one would be motivated to employ the compounds/compositions of Shinitzky's to obtain the instant compounds of formula (I), wherein the variable n is 1. Dependent claims 16-28 are also rejected along with claim 1 under the obviousness-type double patenting.

The motivation to obtain the claimed compounds/compositions derives from known Shinitzky's compounds would possess similar activities (i.e., agents as pharmaceuticals) to that which is claimed in the reference.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### *Claim Objections*

**10**. Claims 21-25 are objected to for being substantial duplicates of the claims from which they depend. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k). It is noted that claims 21-25 are drawn to a pharmaceutical compositions as claim 20.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

October 29, 2007